Department of Public Health

Division of Health Care Quality
and
Drug Control Program

Policy on Return for Redispensing of Medications from Long Term Care Facilities

Background

In accordance with M.G.L. c. 111, §25I, the Department of Public Health (Department), permits long term care facilities (LTCFs) licensed by the Department to return unused unit-dose packaged[1] and certain other unused Schedule VI[2] and over-the-counter medications to pharmacies for the purpose of redispensing to patients or residents. Department policy also permits LTCFs to utilize a unit-dose packaging for management and administration of pharmaceuticals to patients or residents.[3]

The Department, working with the Board of Registration in Pharmacy[4], has determined that the return for redispensing of unit-dose packaged medications can be a safe and effective method of pharmaceutical distribution. The return for redispensing of unit-dose packaged medications may contribute to the reduction of medication waste.[5]

Department regulations and this policy govern only the return for redispensing of medications from LTCFs to pharmacies. Regulations of the Board of Registration in Pharmacy govern the receipt and redispensing of such returned medications.

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[1] Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form. Labeling is in accordance with United States Pharmacopeia standards compendia and federal and state law. For purposes of this policy traditional "bingo cards" or "bubble packs" are considered an assemblage of multiple, unlabeled, single doses and are not considered to be unit-dose packaging.

[2] Schedule VI medications refers to all prescription medications that are not in federal Schedules II - V.

[3] Department of Public Health *Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities.*

[4] Board of Registration in Pharmacy, 239 Causeway St., Boston 02114.

[5] Department of Public Health Report, May 31, 1996, *Special Project: Dispensing of Unit Dose Medications in LTCFs.*

Requirements

1) The LTCF must have a written policy regarding the return for redispensing of Schedule VI and over-the-counter medications. The policy must address patient or resident safety issues including but not limited to:

   A) ensuring the integrity of drugs subjected to extended and repeated handling, storage and transportation;
   B) ensuring dispensers, repackagers and ultimate users can be identified and notified in the event of a recall;
   C) minimizing opportunities for tampering and diversion; and
   D) ensuring that all medications are stored in accordance with the standards of the United States Pharmacopeia (USP);

2) Drug products that may be returned are limited to:

   A) intact, solid oral dosage forms, in unit-dose packaging and packaged as follows:
      i) by the original manufacturer; or
      ii) by the pharmacy in accordance with industry standards;
   B) ampules;
   C) suppositories;
   D) parenteral medications in single-dose sealed containers; and
   E) medications in multi-dose sealed containers[6], that are dispensed pursuant to an order for an individual patient or resident and from which no doses have been withdrawn;

3) The following must be indicated clearly on each individual unit:

   A) if a single active ingredient, the established name of the drug and the quantity of the active ingredient per dosage unit;
   B) if a combination drug, the established name and quantity of each active ingredient per dosage unit;
   C) lot or control number;
   D) expiration or beyond use date;
   E) NDC number or equivalent information; and
   F) any special storage and handling instructions required by USP standards or state or federal law;

4) The following drug products may not be returned to a pharmacy for redispensing:

   A) compounded or reconstituted drugs;
   B) drugs that require refrigeration;
   C) drugs that are adulterated or misbranded;
   D) drugs which have had their integrity, packaging or labeling compromised (e.g., through environmental damage such as water damage, crushing, a broken seal, a torn or marked label); and
   E) drugs designated as Schedule II - V controlled substances in accordance with M.G.L. c. 94C, §3.

[6] Injectables, ophthalmics and topicals packaged and sealed by the original manufacturer.

5) Medications must be returned to the pharmacy (including location) from which they were originally dispensed;

6) Drug products must be returned within 30 days of discontinuation of use by a patient or resident;

7) Drug products must be returned no less than 90 days prior to the beyond use date or expiration date, whichever is earlier;

8) The LTCF must establish tracking and recordkeeping systems for returned medications:

   A) Records must include:
      i) the date returned to the pharmacy;
      ii) prescription number under which the unused medication was originally dispensed;
      iii) identity and strength of drug product;
   B) This information must be made available to the Department upon request; and
   C) These records shall be kept on file for a period of two years; and

9) In accordance with M.G.L. c. 111, §25I, the pharmacy to which such medication is returned shall reimburse or credit the purchaser for any such returned medication.